IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

JOANN BURKEEN and LUCINDA ISOM, Plaintiffs, -vs- PFIZER, INC.; PHARMACIA CORPORATION; and G.D. SEARLE LLC (FKA G.D. SEARLE & CO.), Defendants.	Civil No. **JURY TRIAL DEMANDED**

COMPLAINT

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COMPLAINT

Plaintiffs, for their Complaint against Defendants, allege as follows:

I. INTRODUCTION.

1. This is a civil action seeking damages for personal injuries. The Plaintiffs assert product liability claims against Defendants PFIZER, INC., PHARMACIA CORPORATION; and G.D. SEARLE LLC (FKA G.D. SEARLE & CO.), (hereinafter referred to as "PFIZER") arising from the design, manufacture, and sale of a drug known as Celebrex ("CELEBREX"). It is alleged by the Plaintiffs that CELEBREX was a defective and unreasonably dangerous product that caused their damages.

2. It is anticipated that these actions will be subject to transfer and consolidation for pretrial proceedings pursuant to 28 U.S.C.A. §1407 in the United States District Court for the District of Minnesota. *See In Re: Bextra and Celebrex Product Liability Litigation,* MDL 1699 (J.P.M.D.L., *filed* Sept. 6, 2005) (transfer order, attached as Exhibit "A"). Plaintiffs join their individual and several claims against Defendants into this one lawsuit because their claims arise out of the same transaction, occurrence, or series of transactions or occurrences and questions of law and fact common to all Plaintiffs will arise in this action. FED. R. CIV. P. 20(a). Joinder of these parties and claims for transfer and pretrial proceedings would work to "secure the just, speedy, and inexpensive determination of [this] action." FED. R. CIV. P. 1. Therefore, Plaintiffs have joined their claims in this Complaint.

II. **THE PARTIES.**

A. **The Individual Plaintiffs.**

3. Plaintiff, **JOANN BURKEEN**, is an adult individual residing in Tennessee.

4. Plaintiff, **LUCINDA ISOM**, is an adult individual residing in Tennessee.

B. **The Defendants PFIZER, INC.; PHARMACIA CORPORATION; and G.D. SEARLE LLC (FKA G.D. SEARLE & CO.).**

5. Defendant **PFIZER, INC.**, is a foreign, for-profit corporation. PFIZER, INC. is incorporated in Delaware and has its principal place of business in New York, New York. At all times material, PFIZER, INC. was and is in good standing and actively doing business in the State of Minnesota. On July 16, 2002, PFIZER, INC. announced its proposed acquisition of PHARMACIA CORPORATION ("PHARMACIA"). On April 16, 2003, PFIZER, INC. completed its $60 billion acquisition of PHARMACIA. As a wholly-owned subsidiary of PFIZER, INC., PHARMACIA acted in all aspects as PFIZER's agent and alter ego. At all relevant times, PFIZER, INC. and/or its predecessors-in-interest were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting and selling the drug Celecoxib under the trade name CELEBREX in Minnesota and throughout the United States.

6. Defendant **G.D. SEARLE LLC (FKA G.D. SEARLE & CO.)** ("SEARLE") is a Delaware corporation with its principal place of business in Illinois. In April 2000, SEARLE was acquired by PHARMACIA and became a wholly-owned subsidiary of PHARMACIA. At the time of PFIZER, INC.'s acquisition of

PHARMACIA, SEARLE was a wholly-owned subsidiary of PHARMACIA, acting as its agent and alter ego in all matters alleged in this Complaint, and is now a wholly-owned subsidiary of PFIZER, INC. At all relevant times, SEARLE has been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting and selling the drug Celecoxib under the trade name CELEBREX in Minnesota and throughout the United States.

7. Defendant **PHARMACIA CORPORATION** is a Delaware corporation with its principal place of business in New Jersey. PHARMACIA was created in April 2000 through the merger of Pharmacia & Upjohn with Monsanto Company and its G.D. SEARLE unit. PHARMACIA is now a wholly-owned subsidiary of PFIZER, INC.. At all relevant times, PHARMACIA, and its predecessors-in-interest have been engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting and selling the drug Celecoxib under the trade name CELEBREX in Minnesota and throughout the United States.

8. Celecoxib was developed in 1998 by SEARLE and marketed jointly by SEARLE and PFIZER, INC. under the brand name CELEBREX. SEARLE was acquired by PHARMACIA, which was then acquired by PFIZER, INC., in part so that PFIZER, INC. could take full control of CELEBREX.

9. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted and misrepresented the risks, dangers, defects and disadvantages of CELEBREX, and advertised, promoted, marketed, sold and distributed CELEBREX as a safe prescription medication when, in fact, Defendants had reason to know, and did know, that CELEBREX was not safe for its intended purposes,

for the patients for whom it was prescribed and for whom it was sold and that CELEBREX caused serious medical problems, and in certain patients, catastrophic injuries and deaths.

10. In engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other Defendants, or those Defendants' predecessors-in-interest.

III. JURISDICTION AND VENUE.

11. This Court has subject matter jurisdiction under 28 U.S.C.A. §1332 (diversity jurisdiction). Plaintiffs and PFIZER are citizens of different states and the amount in controversy exceeds $75,000.00.

12. This Court has personal jurisdiction over PFIZER who, at all times material, was and is licensed and registered to do business in Minnesota. PFIZER, INC. maintains a registered agent for the service of process in Minnesota: CT Corporation System, Inc., 405 2nd Avenue South, Minneapolis, MN 55401. Plaintiffs, by bringing this action, submit to this Court's personal jurisdiction.

13. As this is a case is based upon diversity jurisdiction, this Court applies the forum state's choice-of-law rules. *Glover v. Merck & Co., Inc.*, 345 F.Supp.2d 994, 997 (D. Minn. 2004). Therefore, Minnesota choice-of-law principles apply here. *Id.*

14. As it relates to statutes of limitation, the traditional rule in Minnesota is that such statutes are procedural and governed by the law of the forum. *Id.*

15. Venue is proper in this District pursuant to 28 U.S.C.A. §1391. PFIZER marketed, advertised and distributed the dangerous product in this District, thereby receiving substantial financial benefit and profits from sales of the dangerous product in

this District and reside in this District under 28 U.S.C.A. §1391(c), such that venue is proper.

16. At all relevant times herein, PFIZER was in the business of designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing, warranting and selling their product, CELEBREX. PFIZER at all times relevant hereto designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce (including Minnesota) the aforementioned prescription drug. PFIZER does substantial business in the State of Minnesota and within this District, advertises in this District, receives substantial compensation and profits from sales of CELEBREX in this District and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District. In engaging in the conduct herein, each Defendant acted as the agent for each of the other Defendants or those Defendants' predecessors-in-interest.

IV. FACTS COMMON TO ALL PLAINTIFFS.

A. Facts Regarding CELEBREX: Science and Other COX-2 Inhibitors.

17. CELEBREX is among a class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve®) and ibuprofen (trade name Advil®) are examples of well-known NSAIDs.

18. NSAIDs reduce pain and inflammation by blocking the body's production of pain transmission enzymes called cyclooxygenase, COX-1 and COX-2. COX enzymes trigger the sequential oxidation of various fatty acids to create prostaglandins. Prostaglandins are important cogs in the physiology of pain, igniting hormone-like

actions in the immediate vicinity of the cells that release them, thereby inducing inflammation, pain and fever.

19. Because COX enzymes and prostaglandins increase the pain associated with tissue injury, the synthesis of prostaglandins by cells of injured tissue becomes a reasonable target for pain-management drugs.

20. Traditional NSAIDs like aspirin, ibuprofen and naproxen inhibit both COX-1 and COX-2 enzymes simultaneously, providing relief from inflammation and pain, but at the cost of potential adverse gastrointestinal effects, as the prostaglandins that are supported by COX-1 enzymes are involved in the production of gastric mucus which protects the stomach wall from the hydrochloric acid present in the stomach. By blocking the COX-1 enzyme, the body's ability to protect gastric tissue is hampered and, as a result, can cause harmful gastrointestinal side effects, including stomach ulceration and bleeding.

21. PFIZER and other pharmaceutical companies set out to remedy these gastrointestinal side effects suffered by some NSAID users by developing "selective" inhibitors, called coxibs, which targeted only COX-2 production, thus (allegedly) allowing for proper maintenance of gastric tissue while still reducing inflammation. Their development was based on the hypothesis that COX-2 was the source of prostaglandins E2 and I2, which mediate inflammation, and that COX-1 was the source of the same prostaglandins in the stomach lining. By not inhibiting COX-1, whose products provide cytoprotection in the gastric epithelium; these coxibs were thought to decrease the incidence of gastric side effects when compared to traditional NSAIDS that inhibit both COX-1 and COX-2.

22. In making this decision, however, PFIZER and their predecessors-in-interest either intentionally ignored and/or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostaglandin I2 levels, the predominant COX-2 product responsible for preventing platelet aggregation, clotting and vasoconstriction, while leaving thromboxane A2 (a potent COX-1 platelet aggregator and vasoconstrictor), unaffected. By selectively inhibiting COX-2 (prostaglandin I2) without similarly suppressing its COX-1 counterpart, CELEBREX and other coxibs expose their users to a host of clot-related cardiovascular risks, including heart attack, stroke, unstable angina and serious thromboembolic events.

23. On June 29, 1998, SEARLE and PFIZER filed for the U.S. Food and Drug Administration ("FDA") approval of Celecoxib, its first major COX-2 inhibitor drug, under the trade name CELEBREX. The FDA granted preliminary approval of the new drug on December 31, 1998, for the relief of signs and symptoms of adult osteoarthritis and rheumatoid arthritis. A year later, on December 23, 1999, the FDA granted accelerated approval of CELEBREX for a second indication; the reduction of intestinal polyps as an adjunct to endoscopy and surgery in patients with familial adenomatous polyposis (FAP), a rare genetic disorder.

24. In late January 1999, following FDA approval, PFIZER publicly launched CELEBREX, their new "blockbuster" drug, in one of the largest direct-to-consumer marketing campaigns ever undertaken for prescription drugs. PFIZER's massive marketing campaign fraudulently and misleadingly depicted CELEBREX as a much safer and more effective pain reliever than less inexpensive traditional NSAIDs. PFIZER, its

representatives and agents misrepresented the safety profile of CELEBREX to consumers, the medical community, healthcare providers and third party payors.

B. Facts Regarding CELEBREX's Safety and PFIZER's Knowledge Thereof.

25. The potential for cardiovascular risk of selective COX-2 inhibitors was known to PFIZER long before the FDA granted market approval in December 1998. By 1997, and prior to the submission of the New Drug Application (the "NDA") for CELEBREX, PFIZER was aware that, by selectively inhibiting only the COX-2 enzyme, CELEBREX altered the homeostatic balance between prostacylcin synthesis and thromboxane and thereby increased the prothrombotic effects of the drugs, causing blood clots to form in those who ingested it. *See* Topol, E.J., *et al.*, "*Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*," JAMA, August 22, 2001 at 954.

26. Pharmacologist Dr. Garrett Fitzgerald of the University of Pennsylvania reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004, that contemporaneous with PFIZER's launch it was known that selective COX-2 inhibitors, such as CELEBREX, suppressed the formation of prostaglandin I-2 in healthy volunteers, inhibited platelet aggregation in vitro and may predispose patients to myocardial infarction or thrombotic stroke. Fitzgerald, G.A., Patrono C., "*The Coxibs, Selective Inhibitors of Cyclooxygenase-2*," N Engl J Med 2001;345:433-442.

27. Early FDA updates in March and April of 1999 similarly acknowledged this known risk, but noted, based upon PFIZER's representations, that CELEBREX "does not affect platelet aggregation (clumping), an important part of the blood clotting

process." *See* FDA Updates, *"New Arthritis Drug May Have Fewer Side Effects,"* FDA Consumer March-April 1999.

28. Based on the studies performed on CELEBREX, other COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely conducted, PFIZER knew when CELEBREX was being developed and tested that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors.

29. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new studies specifically analyzing the risks of CELEBREX, PFIZER failed to take any action to protect the health and welfare of patients, opting instead to continue promoting the drug for sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory Committee meetings.

C. CELEBREX and COX-2 Studies Did Not Show CELEBREX to be Safe.

1. CELEBREX Long-Term Arthritis Safety Study (CLASS).

30. In September 1998, PHARMACIA sponsored an allegedly independent CELEBREX Long-Term Arthritis Safety Study ("CLASS"). The multicenter, double-blind, parallel group study sought to compare the incidence of clinically significant upper gastrointestinal events between CELEBREX 400 mg BID and Ibuprofen 800 mg. (CLASS data is found in NDA 20-998/S-009 submitted to the FDA by SEARLE on June 12, 2000. CLASS was submitted to the FDA on June 12, 2000 and reviewed by James Witter, M.D., Ph.D. (FDA Medical Officer) on September 20, 2000.)

31. On September 13, 2000, PFIZER released the results of the CLASS study in the *Journal of American Medicine.* Silverstein, F.E., *et al.*, "*Gastrointestinal Toxicity with Celecoxib vs. Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis: The CLASS Study: A Randomized Controlled Trial,*" 284 JAMA 1247 (2000). Researchers enthusiastically reported a "lower incidence of symptomatic ulcers and ulcer complications combined, as well as other clinically supported toxic effects, compared with NSAIDs at standard doses."

32. Although PFIZER touted the CLASS study as the primary evidence to support its theory that CELEBREX was safer for consumers who could not tolerate traditional NSAIDs in their gastrointestinal system, PFIZER intentionally, recklessly and/or negligently concealed, suppressed, omitted and misrepresented the results, risks and defects of the CLASS study. Among other things, PFIZER failed to release the study's complete twelve month results – releasing only the first six months of trials, reported biased and misleading results, limited conclusions to upper gastrointestinal events despite other known risks factors and understated known cardiovascular risks.

33. Despite PFIZER's favorable CLASS Study conclusions, no other reviewing or administrative body was able to substantiate those findings. The FDA Medical Officer Review of the CLASS data found CELEBREX to be no more efficacious than other traditional NSAIDS comparators. *See generally*, FDA Medical Officer Review, NDA 20-998/S-009 submitted to the FDA by SEARLE on June 12, 2000. According to the FDA's review of the CLASS data: "Celecoxib did not demonstrate any statistical superiority to NSAIDs (pooled) or either comparator (diclofenac and ibuprofen) with regards to the primary safety endpoint of CSUGIE (Clinically Significant

Upper Gastrointestinal Adverse Events) at any point in the trial although there were trends that favored celecoxib." (FDA CLASS Review).

34. The FDA Arthritis Advisory Committee similarly found no "clinically meaningful" safety advantage of CELEBREX over older NSAIDs. (FDA CDER Arthritis Advisory Committee, February 7th and 8th, 2001, Gaithersburg, Maryland). The CLASS Study failed to demonstrate a superior safety record over ibuprofen or pooled NSAID data. Based on this information, the Committee advised that further studies be done to assess the risk of COX-2 drugs and NSAIDS when taken with aspirin.

35. In a June 2002 editorial, the *British Medical Journal* chastised the Study's "misleading" and "seriously biased" nature, noting that the complete results "clearly contradict[ed] the published conclusions" and warning against the dangers of "overoptimistic," "short-term" data and "post hoc changes to the protocol." Juni, Peter, *et. at., "Are Selective COX 2 Inhibitors Superior to Traditional Non Steroidal Anti-Inflammatory Drugs?"* BMJ 2002;324:1287-1288. Most noticeably, the CLASS study considered only six months of data despite the fact that researchers at that point had 12 months of data that, when analyzed as a whole, showed no significant difference. Instead of releasing the complete 12-month results from CLASS, PFIZER relied on and published only the first six months of data. JAMA 2000, 48:1455-1460. The results of the completed study revealed the real truth: CELEBREX offered no gastrointestinal (GI) benefit. Almost all ulcer-related complications that had occurred during the second half of the CLASS trials were in users of CELEBREX. These results clearly contradict the published CLASS conclusions.

36. Editors of the Journal of the American Medical Association (JAMA) and other medical experts were reportedly "flabbergasted" when they realized they had been "duped" by only being provided with the first six months of CLASS data. Okie S., *"Missing data on Celebrex: Full study altered picture of drug,"* Washington Post 2001 Aug 5;Sect A:11. The *Washington Post* reported JAMA editors noting: "When all of the data were considered, most of CELEBREX's apparent [GI] safety advantage disappeared."

37. Institutional bias also appeared to play a role in the Study's biased conclusions. According to the *Washington Post*, all 16 CLASS authors were either employees of PHARMACIA or paid consultants of the company. Okie, S., *"Missing data on Celebrex: Full study altered picture of drug,"* Washington Post 2001 Aug 5;Sect A:11. Moreover, at least one author, Dr. M. Michael Wolfe, a gastroenterologist from Boston University, admits he was duped by PHARMACIA. In the summer of 2000, *The Journal of the American Medical Association* asked Wolfe to participate in the "six-month" trial. Wolfe found the study, tracking 8,000 patients over a six-month period, persuasive, and penned a favorable review, which helped to drive up CELEBREX sales. It was not until early the next year, while serving on the FDA's Arthritis Advisory Committee, that Wolfe learned the study had run for one year, not six months, as the company had originally led both Wolfe and the *Journal* to believe. *Id.* Here again, when the complete data was considered, most of CELEBREX's advantages disappeared.

38. PFIZER also limited conclusions of the CLASS study to upper gastrointestinal events, despite other known risks factors, and understated known cardiovascular risks. A metastudy by the Cleveland Clinic published in the Journal of the

American Medical Association analyzed data from two major studies, including CLASS, funded by the drug companies and two smaller ones – all for cardiovascular risks. Debabrata Mukherjee, *et al.*, "*Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*," 286 JAMA 954 (2001).) The metastudy found that PHARMACIA failed to identify and study cardiovascular risks for their products. The annualized heart attack rates for patients taking Vioxx or CELEBREX, the researchers found, were "significantly higher" than those in a group taking placebos. "The available data raise a cautionary flag about the risk of cardiovascular events with Cox-2 inhibitors," they concluded.

39. "A total of 36 deaths occurred during the [CLASS] study or during post study follow-up: 19 in the celecoxib group, 9 in the diclofenac group and 8 in the ibuprofen group . . . . Most deaths were cardiovascular in nature." FDA CLASS Review at 54. The increased number of adverse cardiovascular events in the CELEBREX group was not surprising, as they were also revealed in the original New Drug Application (NDA) submitted for CELEBREX. "In the original NDA, myocardial infarction was noted to occur at a higher rate in celecoxib-treated as compared to placebo-treated patients. In the long term trial (Trial 024) that was included in the NDA submission, the predominate (>90%) cause of death for patients taking celecoxib at any dose was cardiovascular." FDA CLASS Review at 78.

40. Public Citizen, a public watchdog organization, also reviewed the CLASS data in its entirety. A complete review reveals the combined anginal adverse events were 1.4% in the CELEBREX group versus 1.0% in either NSAID group. Specifically, the

rate of heart attack in the CELEBREX was double that of the other two NSAIDs, 0.2% vs. 0.1%, respectively.

41. Eric Topol of the Cleveland Clinic reached a similar conclusion, noting that the CLASS trial MI rate was 1.6% in CELEBREX group (at a dosage of 400 mg twice a day) and 1.2% in the ibuprofen group for the 1739 patients taking low-dose aspirin. Topol noted that this numerical excess, albeit not statistically significant, was also found in the 6229 patients not taking aspirin in the trial. Eric J. Topol, *"Arthritis Medicines and Cardiovascular Events – House of Coxibs,"* JAMA 293:366. Based on this data, Topol and his colleagues concluded: "It is mandatory to conduct a trial specifically assessing cardiovascular morbidity." *Id.* Unfortunately, no such trials were ever initiated, delaying the official warnings of CELEBREX and jeopardizing countless lives in the process.

42. The CLASS data proves that PFIZER knew that its first generation COX-2 inhibitor, CELEBREX, caused a disproportionately and statistically significant high number of adverse cardiovascular events before it was introduced to the market in January 1999. According to Public Citizen, after CLASS, the FDA recommended a trial to specifically assess the cardiovascular risks of COX-2 inhibitors. The Adenoma Prevention with Celecoxib (APC) trial was intended to be this placebo-controlled trial of CELEBREX.

2. <u>APC Trial.</u>

43. In early 2000, the National Cancer Institute (NCI), in collaboration with SEARLE and PFIZER, initiated the APC trial, a randomized, double-blind, placebo-controlled study to discover the efficacy of CELEBREX in preventing the growth of pre-

cancerous colon polyps. N.ENG. J. MED. 352;11 at 1072. The trial involved 2026 patients across the country with randomization to one of three groups: (1) placebo; (2) 200 mg CELEBREX twice daily; and (3) 400 mg CELEBREX twice daily. The patients, each of whom had an adenomatous polyp removed before enrollment, were followed up for a mean of 33 months while taking the study drug, with the primary objective of limiting the development of colorectal cancer.

44. On December 17, 2004, the NCI suspended the use of CELEBREX for all participants in the APC trial due to "significant excess of cardiovascular death, myocardial infarction (MI) and stroke." Eric J. Topol, "*Arthritis Medicines and Cardiovascular Events – House of Coxibs,*" JAMA 293:366. Analysis by an independent Data Safety Monitoring Board (DSMB) showed a two to three fold increased risk of major fatal and non-fatal cardiovascular events for participants taking the drug compared to those on a placebo with a secondary dose-response effect.

45. The absolute excess of major cardiovascular events of 13/1000 patients at the 800 mg dose (400 mg 2x day) was strikingly similar to the results of trials with rofecoxib and valdecoxib, both selective NSAID COX-2 inhibitors removed for the market for their significant cardiovascular risks. Eric J. Topol, *"Arthritis Medicines and Cardiovascular Events – House of Coxibs,"* JAMA 293:366.

46. The FDA reported similar results, noting:

> In the National Cancer Institute's Adenoma Prevention with Celecoxib (APC) trial in patients at risk for recurrent colon polyps, a 2-3 fold increased risk of serious adverse CV events was seen for CELEBREX compared to placebo after a mean duration of treatment of 33 months. There appeared to be a dose response relationship, with a hazard ratio of 2.5 for CELEBREX 200 mg twice daily and 3.4 CELEBREX 400 mg twice daily for the

> composite endpoint of death from CV causes, myocardial infarction (MI), or stroke.

April 7, 2005 FDA Alert: www.fda.gov/cder/drug/infopage/celebrex/celebrex-hcp.htm.

47. The dosage noted in the study is itself important for two reasons: first, there appears to be an association between dosage and the increase in adverse cardiovascular events; second, most patients increase dosage. PFIZER knew patients were increasing their dosages as noted in the CLASS Study: "Interestingly ... up to 70% of patients increased their dose for celecoxib." FDA CLASS Review at 74. Thus, PFIZER was aware of "dosage creep."

3. Other CELEBREX Trials.

48. Several other CELEBREX trials also gave PFIZER insight into the cardiovascular risks presented by CELEBREX. The Prevention of Spontaneous Adenomatous Polyps (PreSAP) trial identified the death rate from cardiovascular causes (heart attack, stroke, heart failure, angina, or need for CV procedure) as 3.6% with CELEBREX as compared to 2.7% for placebo.

49. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which reflected "the combined rate of all serious cardiovascular adverse events in patients getting a placebo was 2.1% but was greatly increased in those getting celecoxib to 7.7%, a 3.6 fold increase in CV risk in those people taking celecoxib. (p=0.03)." *Public Citizen*, January 26, 2005, Dr. Sidney M. Wolfe. According to Dr. Sidney Wolfe, "The study revealed a significantly increased rate (3.6-fold) of serious CV adverse events and more than a doubling in the rate of CV deaths in people using celecoxib compared to those using placebo." Id.

4. **COX-2 Studies: VIGOR and APPROVe.**

50. PFIZER also had access to other data which indicated a cardiovascular risk with its drugs. Specifically, PFIZER had knowledge of two studies conducted by Merck related to its COX-2 inhibitor Vioxx – Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp Prevention (APPROVe).

a. **VIGOR.**

51. In 2000, The FDA Medical Officer Review of CLASS specifically noted the VIGOR trial and the concern over serious adverse cardiovascular events. FDA CLASS Review at 78.

52. According to VIGOR (near acronym for Vioxx Gastrointestinal Outcomes Research) Vioxx patients experienced 20% more serious clinical adverse events (statistically significant), they experienced 4.6 times more hypertension events serious enough to warrant discontinuation, 1.7 times more edema events, and 1.85 times as many congestive heart failure adverse events. By two measures of cardiovascular events related to blood clots, Vioxx had twice the risk of naproxen and the results were considered statistically significant.

53. The VIGOR study comprised the most definitive scientific evidence ever obtained about pharmaceutical products. It was a large, randomized clinical trial, the gold standard of medical research. It was a safety study with endpoints set in advance. As Merck stated many times, it was designed to provide definite proof of safety, convincing enough to silence the most skeptical critics. In medical terms, the VIGOR results raised the question of whether selective inhibition of COX-2 was a monumental mistake from the start. While the NSAID risks to the GI system were real and sometimes

fatal, they were dwarfed by the cardiovascular risks of the arthritis population that needed these drugs on a daily basis. All makers of NSAIDs, including PFIZER, were aware of these results.

b. APPROVe.

54. ~~Anxious to put safety questions surrounding Vioxx to rest, Merck~~ designed another large scale trial, Adenomatous Polyp Prevention (APPROVe), which was intended to test the drug's ability to prevent or shrink colon polyps, but would also compare the cardiovascular safety of Vioxx to a placebo control. According to the analysis conducted by Public Citizen of the APPROVe data: Vioxx "doubled the risk of any thrombotic cardiovascular event" and "doubled the risk of MI (myocardial infarction a/k/a heart attack)."[1] *Public Citizen*, January 24, 2005, at 15. Despite the available CELEBREX data and other information related to Vioxx, PFIZER never paused to reevaluate the CELEBREX data and studies.

55. The scientific data available during and after CELEBREX's approval process made clear to PFIZER that their formulation of CELEBREX would cause a higher risk of blood clots, stroke and/or myocardial infarctions among CELEBREX consumers, alerting them to the need to do additional and adequate safety studies.

56. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine*, outlining PFIZER's failure to have conducted the necessary trials before marketing to humans "it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of (COX-2 inhibitors). Such a trial needed to be

[1] Although Merck claims that the two-fold risk of heart attacks and strokes seen in the APPROVe trial did not emerge until after patients had been taking the drug for 18 months, closer analysis indicates that significant increase in risk of heart attack was evident in as little as 4 months time.

conducted in patients with established coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further cardiovascular events."

57. Dr. Topol was also the author on the study published in August 2001 in JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who used COX-2 inhibitors.

58. Based upon readily available scientific data, PFIZER knew, or should have known, that their pre-approval testing of CELEBREX did not adequately represent the cross-section of individuals who were intended consumers and therefore, likely to take CELEBREX. Therefore, PFIZER's testing and studies were grossly inadequate.

59. Had PFIZER done adequate testing prior to approval and market launch, rather than the extremely short duration studies done on the small size patient base that was actually done, the PFIZER's scientific data would have revealed significant increases in incidence of strokes and myocardial infarctions among the intended and targeted population of CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed serious side effects. PFIZER should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

60. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but PFIZER intentionally suppressed this information in order for them to gain significant profits from continued CELEBREX sales.

61. PFIZER's failure to conduct adequate testing and/or additional testing prior to market launch was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

62. At the time PFIZER manufactured, advertised and distributed CELEBREX to consumers, PFIZER intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke, serious thromboembolic events and/or myocardial infarctions because PFIZER knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would purchase other cheaper and safer NSAIDs.

D. Facts Regarding PFIZER's Marketing and Sale of CELEBREX.

63. Such an ineffective and unreasonably dangerous drug could only be widely prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the PFIZER's marketing campaign was fraudulent and misleading. But for fraudulent and misleading advertising, consumers, including the Plaintiffs, would not have purchased CELEBREX, a more costly prescriptive drug, ineffective for its intended purposes.

64. PFIZER's marketing was so fraudulent that the FDA issued three Warning Letters to PFIZER in October 1999, April 2000 and November 2000, all finding that PFIZER was unlawfully making false or misleading statements concerning the safety and/or efficacy of CELEBREX. The November letter cited two direct-to-consumer television advertisements that overstated the efficacy of CELEBREX. The FDA ordered that SEARLE immediately cease distribution of the misleading ads.

65. On February 2001, the FDA issued a Warning Letter to PHARMACIA stating that promotional activities from marketing CELEBREX were unlawful because they were "false, lacking in fair balance, or otherwise misleading." The FDA found that CELEBREX had been promoted for unapproved uses, in unapproved dosing regiments and that the marketers had made unsupportable claims that CELEBREX was safer and more effective than other NSAIDs.

66. In August 2001, it was revealed that PHARMACIA had misrepresented the results of a post-marketing clinical study of CELEBREX when submitting it for publication. PHARMACIA selectively omitted portions of the data relating to adverse effects. The *Washington Post* reported on August 5, 2001, that, "the study had lasted a year, not six months as . . . thought. Almost all of the ulcer complications that occurred during the second half of the study were in CELEBREX users. When all of the data were considered, most of CELEBREX's apparent safety advantage [as compared to traditional NSAIDs] disappeared."

67. On January 10, 2005 the FDA again issued PFIZER a written reprimand for its promotional activities. The reprimand reads: "These five promotional pieces [3 CELEBREX and 2 CELEBREX] variously: omit material facts … and make misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims." Amid continued frustration with PFIZER's continually misleading marketing strategy and ever surmounting evidence of cardiovascular dangers, the FDA Advisory Panel voted overwhelmingly that the company should never again advertise the drug [CELEBREX].

68. At all times relevant herein, PFIZER engaged in a marketing campaign with the intent that consumers would perceive CELEBREX as a safer and better drug than its other NSAIDs and, therefore, purchase CELEBREX.

69. PFIZER widely and successfully marketed CELEBREX throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of CELEBREX in order to induce a widespread use and consumption. CELEBREX was represented to aid the pain and discomfort of arthritis, osteoarthritis and related problems. PFIZER made misrepresentations by means of media advertisements and statements contained in sales literature provided to Plaintiffs' prescribing physicians.

70. Despite knowledge of the dangers presented by CELEBREX, PFIZER and PFIZER's predecessors-in-interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of CELEBREX and failed to warn the public, including Plaintiffs, of the serious risk of injury occasioned by the defects inherent in CELEBREX. PFIZER and its officers, agents and managers intentionally proceeded with the inadequate safety testing, and then the manufacturing, sale and marketing of CELEBREX, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. PFIZER's conduct was wanton and willful and displayed a conscious disregard for the safety of the public and particularly of Plaintiffs.

71. In an elaborate and sophisticated manner, PFIZER aggressively marketed CELEBREX directly to consumers and medical professionals (including physicians and

leading medical scholars) in order to leverage pressure on third party payors, medical care organizations and large institutional buyers (*e.g.*, hospitals) to include CELEBREX on their formularies. Faced with the increased demand for the drug by consumers and health care professionals that resulted from PFIZER's successful advertising and marketing blitz, third party payors were compelled to add CELEBREX to their formularies. PFIZER's marketing campaign specifically targeted third party payors, physicians and consumers and was designed to convince them of both the therapeutic and economic value of CELEBREX.

72. PFIZER represented that CELEBREX was similar to ibuprofen and naproxen but was superior because it lacked any of the common gastrointestinal adverse side effects associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). PFIZER promoted CELEBREX as a safe and effective alternative that would not have the same deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief.

73. Yet, CELEBREX possessed dangerous and concealed or undisclosed side effects, including the increased risk of serious cardiovascular events, such as heart attacks, unstable angina, myocardial infarctions (heart attacks), deep vein thrombosis, pulmonary emboli, hypertension and cerebrovascular events, such as strokes. In addition, CELEBREX is significantly more expensive than traditional NSAIDs (costing $3.00 to $6.00 per day for CELEBREX versus $0.50/day for over the counter NSAIDs). Moreover, CELEBREX was no more effective than traditional and less expensive NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers and gastrointestinal bleeding. Yet, PFIZER chose not to warn about these risks and dangers.

74. PFIZER knew of these risks before the FDA approved CELEBREX for sale, but PFIZER ignored, downplayed, suppressed, omitted and concealed these serious safety risks and denied the lack of efficacy in its promotion, advertising, marketing and sale of CELEBREX. PFIZER's omission, suppression and concealment of this important information enabled CELEBREX to be sold to, and purchased or paid for by, the Consumers at a grossly inflated price.

75. Consequently, CELEBREX captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2004 alone, sales of CELEBREX exceeded $2 billion, despite the significantly higher cost of CELEBREX as compared to other pain relievers in the same family of drugs.

76. Because PFIZER engaged in a promotional and marketing campaign that featured an advertising blitz directly targeted to consumers, that touted CELEBREX as a safer drug than other drugs in its class, while uniformly failing to disclose the health risks of CELEBREX, PFIZER was able to justify pricing CELEBREX significantly higher than the cost of generic aspirin. In reality, that price inflation was not justified. Had PFIZER disclosed the truth about CELEBREX, PFIZER would not and could not have reaped the billions of dollars in CELEBREX sales that were achieved as a direct result of the concealment, omission, suppression, and obfuscation of the truth.

77. PFIZER intentionally, deliberately, knowingly and actively concealed, omitted, suppressed and obfuscated important and material information regarding the risks, dangers, defects and disadvantages of CELEBREX from Plaintiffs, the public, the medical community and the regulators. This concealment and omission was deliberate, knowing, active and uniform, was intended to induce and maximize sales and purchases

of CELEBREX, and prevented Plaintiffs from obtaining all the material information that would be important to their decision as a reasonable person to purchase, pay for and/or use CELEBREX.

78. PFIZER's systematic, active, knowing, deliberate and uniform concealment, omissions, suppression and conduct caused Plaintiffs to purchase, pay for and/or use CELEBREX; and caused Plaintiffs' losses and damages as asserted herein.

79. Had PFIZER done adequate testing prior to approval and "market launch," the PFIZER's scientific data would have revealed significant increases in stroke and myocardial infarction amongst the intended population of CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed serious side effects. PFIZER should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

80. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but PFIZER intentionally suppressed this information in order for them to gain significant profits from continued CELEBREX sales.

81. PFIZER's failure to conduct adequate testing and/or additional testing prior to "market launch," and active concealment and failure to warn the medical community and general public of the known cardiovascular risks of CELEBREX was particularly negligent, reckless and/or malicious given the drug's known target market. PFIZER was well aware that most patients taking CELEBREX are elderly and have higher risk of developing cardiovascular risks to begin with. Nearly half of the patients

with arthritis have coexisting cardiovascular disease, and most patients, as discovered in the CLASS study, were prone to higher dosing.

82. PFIZER's failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

83. At the time PFIZER manufactured, advertised and distributed CELEBREX to consumers including Plaintiffs, PFIZER intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, serious thromboembolic events, stroke and/or myocardial infarctions because PFIZER knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would purchase other cheaper and safer NSAID drugs.

V. INDIVIDUAL PLAINTIFF'S STATEMENT OF FACTS.

A. PLAINTIFF JOANN BURKEEN:

84. Plaintiff JOANN BURKEEN was prescribed CELEBREX on December 19, 2000. She took it daily and was still taking it on February 21, 2002, a period of fourteen months, at which time she was admitted to the hospital complaining of severe pain in her right leg and foot. Ms. Burkeen was diagnosed with a deep vein thrombosis [DVT]. CELEBREX caused or contributed to cause the DVT which she suffered on February 21, 2002, along with other injuries and damages.

85. Unaware of the risks presented by CELEBREX, or that CELEBREX was the cause of her injuries, Ms. Burkeen continued to take CELEBREX until December 19, 2003. Ms. Burkeen and her healthcare providers were, at the time of her injuries,

unaware and could not have reasonably known or have learned through reasonable diligence that such injuries directly resulted from Plaintiff's ingestion of CELEBREX. Plaintiff and her healthcare providers never knew of the significant increased risks of a DVT caused by CELEBREX until various information was released sometime thereafter.

86. As a result of the PFIZER ENTITIES' wrongful acts, Ms. Burkeen suffered severe and permanent personal injuries as described above due to her prescribed consumption of CELEBREX. As a result of the severe and permanent personal injuries as described above, Ms. Burkeen incurred and will continue to incur damages, including but not limited to, medical expenses and other economic losses. Additionally, Ms. Burkeen has endured and will continue to endure pain, suffering, disability, mental anguish and disfigurement, causing additional damages. These damages exceed $75,000.00.

B. PLAINTIFF LUCINDA ISOM:

87. Plaintiff LUCINDA ISOM was prescribed CELEBREX on January 20, 2003. She took it daily and was still taking it on January 14, 2004, a period of twelve months, at which time she was admitted to the hospital complaining of chest pain, right arm pain and nausea. Ms. Isom was diagnosed with an acute myocardial infarction [heart attack]. CELEBREX caused or contributed to cause the heart attack which she suffered on January 14, 2004, along with other injuries and damages.

88. Ms. Isom continued taking CELEBREX after her heart attack on January 14, 2004, for a period of two months at which time she was admitted to the hospital with complaints of right arm pain. Ms. Isom was diagnosed with a second heart attack.

CELEBREX caused or contributed to a second heart attack which she suffered on March 8, 2004, along with other injuries and damages.

89. Unaware of the risks presented by CELEBREX, or that CELEBREX was the cause of her injuries, Ms. Isom continued to take CELEBREX until July 19, 2005. Ms. Isom and her healthcare providers were, at the time of her injuries, unaware and could not have reasonably known or have learned through reasonable diligence that such injuries directly resulted from Plaintiff's ingestion of CELEBREX. Plaintiff and her healthcare providers never knew of the significant increased risks of a heart attack caused by CELEBREX until various information was released sometime thereafter.

90. As a result of the PFIZER ENTITIES' wrongful acts, Ms. Isom suffered severe and permanent personal injuries as described above due to her prescribed consumption of CELEBREX. As a result of the severe and permanent personal injuries as described above, Ms. Isom incurred and will continue to incur damages, including but not limited to, medical expenses and other economic losses. Additionally, Ms. Isom has endured and will continue to endure pain, suffering, disability, mental anguish and disfigurement, causing additional damages. These damages exceed $75,000.00.

VI. CLAIMS FOR RELIEF

A. Count I: Strict Liability.

91. Plaintiffs adopt by reference Paragraphs 1 through 90.

92. PFIZER and its predecessors-in-interest were engaged in the business of researching, designing, producing, manufacturing, testing, inspecting, packaging, advertising, promoting, selling and distributing drugs and pharmaceutical products, particularly including CELEBREX as described above.

93. CELEBREX was and is defective and unreasonably dangerous to persons, like Plaintiffs herein, who might be expected to use the products. CELEBREX was in a defective condition because it was unsafe for normal or anticipated handling and consumption. CELEBREX was unreasonably dangerous as the product was dangerous to an extent beyond that which would be contemplated by the ordinary consumer, like Plaintiffs herein, who purchased it and used it, with the ordinary knowledge common to the community as to its characteristics. CELEBREX was also unreasonably dangerous because the drug, due to its dangerous condition, would not be put on the market by a reasonably prudent manufacturer or seller assuming they knew of its dangerous condition. CELEBREX was defective and unreasonably dangerous in design, manufacturing, instructions, and warnings.

94. CELEBREX was defective and unreasonably dangerous at the time the product left PFIZER's control.

95. CELEBREX was expected to reach and did reach Plaintiffs without substantial change in the condition in which the products were manufactured and sold.

96. The defects in CELEBREX and PFIZER's other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

97. WHEREFORE, Plaintiffs individually demand and pray for judgment against PFIZER in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

B. Count II: Breach of Implied Warranty of Merchantability.

98. Plaintiffs adopt by reference Paragraphs 1 through 97.

99. PFIZER and its predecessors are merchants as to its drugs and pharmaceutical products, particularly including CELEBREX described above. CELEBREX and other drugs and pharmaceutical products are goods.

100. PFIZER, as a merchant, impliedly warranted the merchantability of its drugs and pharmaceutical products, including CELEBREX.

101. CELEBREX was not merchantable as impliedly warranted. Specifically, but not exclusively, CELEBREX was not fit for the ordinary purposes for which it was used because: (1) it caused increased risk of serious thromboembolie, cardiovascular and cerebrovascular adverse events, including heart attacks, strokes, and other serious and harmful adverse health effects, and (2) was not effective in decreasing gastrointestinal side effects.

102. Plaintiffs, as consumers of CELEBREX, were reasonably expected to use, consume and/or be affected by CELEBREX.

103. PFIZER's breach of warranty and other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

104. WHEREFORE, Plaintiffs individually demand and pray for judgment against PFIZER in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

C. Count III: Breach of Implied Warranty of Fitness for a Particular Purpose.

105. Plaintiffs adopt by reference Paragraphs 1 through 104.

106. PFIZER and its predecessors, as merchants and sellers of drugs and pharmaceutical products, including CELEBREX as described above, knew or had reason to know of the particular purpose for which its goods were used.

107. The buyer of CELEBREX relied upon PFIZER's skill and judgment to select and furnish suitable products and goods.

108. As a result, an implied warranty of fitness for a particular purpose existed as to CELEBREX.

109. CELEBREX was not fit for its particular purpose because: (1) it caused increased risk of serious thromboembolie, cardiovascular and cerebrovascular adverse events, including heart attacks, strokes, and other serious and harmful adverse health effects, and (2) was not effective in decreasing gastrointestinal side effects.

110. CELEBREX was not fit for its particular purpose as impliedly warranted causing PFIZER to breach its implied warranty.

111. Plaintiffs, as consumers of CELEBREX, were reasonably expected to use, consume and/or be affected by CELEBREX.

112. PFIZER's breach of warranty and other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

113. WHEREFORE, Plaintiffs individually demand and pray for judgment against PFIZER in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

D. Count IV: Breach of Express Warranty.

114. Plaintiffs adopt by reference Paragraphs 1 through 113.

115. PFIZER expressly represented to Plaintiffs and other consumers and the medical community that CELEBREX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous cardiovascular or other side effects, particularly any unwarned-of side effects, and that it was adequately tested.

1) These warranties came in the form of:

a. PFIZER's public written and verbal assurances of the safety and efficacy of CELEBREX;

b. Press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create an increased demand for CELEBREX, which failed to warn of the risk of injuries inherent to the ingestion of CELEBREX, especially to the long-term ingestion of CELEBREX;

c. Verbal and written assurances made by PFIZER regarding CELEBREX and downplaying the risk of injuries associated with the drug;

d. False and misleading written information, supplied by PFIZER, and published in the Physician's Desk Reference on an annual basis, upon which physicians relied in prescribing CELEBREX during the period of Plaintiffs' ingestion of CELEBREX, and;

e. advertisements.

2) The documents referred to above were created by and at the direction of PFIZER.

3) PFIZER knew or had reason to know that CELEBREX did not conform to these express representations in that CELEBREX is neither as safe nor as effective as represented, and that CELEBREX produces serious adverse side effects.

4) CELEBREX did not and does not conform to PFIZER's express representations because it is not safe, has numerous and serious side effects, including unwarned-of side effects, and causes severe and permanent injuries.

5) Plaintiffs, other consumers and the medical community relied upon PFIZER's express warranties.

6) PFIZER's breach of express warranty and other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

116. WHEREFORE, Plaintiffs individually demand and pray for judgment against PFIZER in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

E. **Count V: Negligence.**

117. Plaintiffs adopt by reference Paragraphs 1 through 116.

118. PFIZER and its predecessors were negligent in preparing, designing, researching, developing, producing, manufacturing, testing, inspecting, packaging, advertising, promoting, selling and/or distributing CELEBREX. PFIZER's negligence included, but is not limited to, the following:

a. PFIZER negligently failed to provide any or adequate and proper warnings as to the dangers of the use of CELEBREX for persons

who were reasonably and foreseeably expected to use CELEBREX, such as Plaintiffs named herein;

b. PFIZER negligently failed to warn and failed to provide adequate instructions for the use of CELEBREX for persons who were reasonably and foreseeably expected to use CELEBREX, such as Plaintiffs herein;

c. PFIZER negligently failed to investigate, perform adequate research and/or test for the hazards of CELEBREX;

d. To the extent that PFIZER may have inquired as to the hazards of CELEBREX, PFIZER negligently failed to convey whatever knowledge or dangers, health hazards or safety precautions it may have had to the prescribers, users and consumers of CELEBREX;

e. PFIZER negligently failed to include adequate warnings with the drug that would alert the medical, pharmaceutical and/or scientific communities and users and/or consumers of the drug, including Plaintiffs, to the potential risks and serious side effects of the drug;

f. PFIZER negligently failed to adequately and properly test and inspect the drug before placing the drug on the market;

g. PFIZER negligently failed to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious side effects, including but not limited to, an increased risk of adverse cardiovascular events and/or death;

h. PFIZER negligently failed to adequately warn the medical, pharmaceutical and/or scientific communities and users and/or consumers of the drug, including Plaintiffs, of the potential risks and other serious side effects associated with the drug, including but not limited to an increased risk of serious thromboembolic and cardiovascular events and/or death;

i. PFIZER negligently failed to conduct adequate pre-clinical testing and research to determine the safety of CELEBREX;

j. PFIZER failed to conduct adequate post-marketing surveillance and exposure studies to determine the safety of CELEBREX;

k. PFIZER negligently failed to provide adequate post-marketing warnings or instructions after PFIZER knew, or should have known, of the significant risks associated with the use of the drug;

l. PFIZER negligently failed to recall and/or remove the drug from the stream of commerce despite the fact that PFIZER knew, or should have known, of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug; and

m. PFIZER negligently encouraged the misuse and overuse of CELEBREX while failing to disclose the side effects of the drug to the medical, pharmaceutical and/or scientific communities and users and/or consumers, including Plaintiffs, in order to make a profit from sales.

119. PFIZER's negligence and other wrongful acts caused or contributed to cause Plaintiffs' injuries and damages as set forth above.

120. WHEREFORE, Plaintiffs individually demand and pray for judgment against PFIZER in an amount exceeding $75,000.00 with such other and further relief as the Court may deem just and equitable.

VII. DEMAND FOR JUDGMENT AGAINST DEFENDANTS PFIZER, INC.; PHARMACIA CORPORATION; and G.D. SEARLE LLC (FKA G.D. SEARLE & CO.).

WHEREFORE, Plaintiffs, JoAnn Burkeen and Lucinda Isom, individually demand judgment of and from PFIZER in an amount in excess of $75,000.00, and seek compensatory damages together with interest, cost of suit and attorney fees and for such other and further relief as the Court deems just and equitable.

VIII. DEMAND FOR JURY TRIAL.

Plaintiffs demand a trial by jury on all claims so triable in this action.

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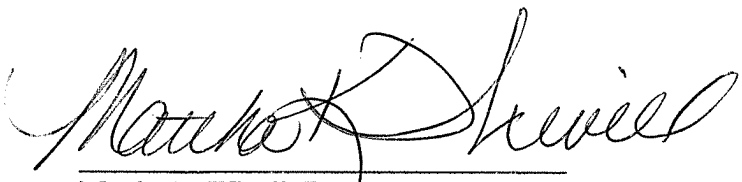

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MDL 1699

RELEASED FOR PUBLICATION

DOCKET NOS. 1691, 1693, 1694 & 1699

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE BEXTRA AND CELEBREX PRODUCTS LIABILITY LITIGATION

IN RE BEXTRA MARKETING AND SALES PRACTICES LITIGATION

IN RE CELEBREX MARKETING AND SALES PRACTICES LITIGATION

IN RE BEXTRA AND CELEBREX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION

BEFORE WM. TERRELL HODGES, CHAIRMAN, JOHN F. KEENAN, D. LOWELL JENSEN, J. FREDERICK MOTZ, ROBERT L. MILLER, JR., KATHRYN H. VRATIL AND DAVID R. HANSEN, JUDGES OF THE PANEL*

TRANSFER ORDER

Before the Panel are five motions, pursuant to 28 U.S.C. § 1407, in these four dockets[1] that taken together seek centralization for coordinated or consolidated pretrial proceedings of all, or a subset of, these 31 actions,[2] in various federal districts. The moving MDL-1691 Louisiana plaintiffs seek centralization of the Bextra and Celebrex products liability actions in the Eastern District of Louisiana, while the moving Connecticut plaintiffs seek centralization of these actions in the District of Connecticut. The moving Southern New York MDL-1693 plaintiff seeks centralization of all Bextra and Celebrex actions in the Southern District of New York. The moving MDL-1694 plaintiffs seek separate centralization of the Bextra actions and the Celebrex actions in the District of Massachusetts before different judges. The moving MDL-1699 Louisiana plaintiffs seek centralization of all Bextra and Celebrex actions in the Eastern District of Louisiana. Most responding plaintiffs agree that centralization is appropriate, although some plaintiffs suggest alternative transferee districts, including the Northern District of California, the District of Delaware, the Southern District of Florida, the District of New Jersey, and the Southern District

* Judge Motz took no part in the decision of this matter.

[1] At the hearing session in these four dockets, the Panel heard combined oral argument. Accordingly, the overlapping issues raised in these dockets are addressed in this one order.

The Panel has been notified of more than 100 potentially related actions pending in multiple federal districts. In light of the Panel's disposition of these dockets, the additional actions will be treated as potential tag-along actions. *See* Rules 7.4 and 7.5, R.P.J.P.M.L., 199 F.R.D. 425, 435-36 (2001).

[2] One additional action, *James Booker v. Merck & Co., Inc., et al.*, N.D. Texas, C.A. No. 3:05-496, was included on the MDL-1691 and MDL-1699 motions. The Panel's decision regarding inclusion of this action in multidistrict proceedings will be addressed in a separate order.

of Texas. Defendant Pfizer Inc. (Pfizer) opposes centralization of the products liability actions, but supports centralization of the marketing/sales practices actions. Pfizer suggests coordination of this latter group of actions (and of the products liability actions, if the Panel deems centralization of these actions to be appropriate) with MDL-1688–*In re Pfizer Inc. Securities, Derivative and "ERISA" Litigation* in the Southern District of New York.

On the basis of the papers filed and hearing session held, the Panel finds that the actions in these four multidistrict dockets involve common questions of fact, and that Section 1407 centralization of all actions as one multidistrict docket (MDL-1699) in the Northern District of California will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. All actions focus on i) alleged increased health risks from taking Celebrex and/or Bextra, anti-inflammatory prescription medications, and ii) whether Pfizer, as the manufacturer of both medications, knew of these increased risks and failed to disclose them to the medical community and consumers and/or improperly marketed these medications to both of these groups. Centralization under Section 1407 is necessary in order to eliminate duplicative discovery, avoid inconsistent pretrial rulings, and conserve the resources of the parties, their counsel and the judiciary. Resolution of overlapping issues, concerning these similar prescription medications manufactured by the same company, will be streamlined. *See In re Managed Care Litigation*, 2000 U.S. Dist. LEXIS 15927 (J.P.M.L. Oct. 23, 2000).

Opponents of Section 1407 centralization of all actions in one multidistrict docket argue that the presence of unique questions of fact relating to each drug (Bextra and Celebrex) or to the type of claims asserted (products liability and marketing/sales practices) should produce a different result. These parties urge us, instead, to separately centralize these actions. We are unpersuaded by these arguments. Transfer under Section 1407 has the salutary effect of placing all actions before a single judge who can formulate a pretrial program that: 1) allows discovery with respect to any non-common issues to proceed concurrently with discovery on common issues, *In re Joseph F. Smith Patent Litigation*, 407 F.Supp. 1403, 1404 (J.P.M.L. 1976); and 2) ensures that pretrial proceedings will be conducted in a manner leading to the just and expeditious resolution of all actions to the overall benefit of the parties. The transferee court can employ any number of pretrial techniques – such as establishing separate discovery and/or motion tracks – to efficiently manage this litigation. In any event, we leave the extent and manner of coordination or consolidation of these actions to the discretion of the transferee court. *In re Mutual Funds Investment Litigation*, 310 F.Supp.2d 1359 (J.P.M.L. 2004). We are confident in the transferee judge's ability to streamline pretrial proceedings in these actions, while concomitantly directing the appropriate resolution of all claims.

Given the geographic dispersal of constituent actions and potential tag-along actions, no district stands out as the geographic focal point for this nationwide docket. Thus we have searched for a transferee judge with the time and experience to steer this complex litigation on a prudent course. By centralizing this litigation in the Northern District of California before Judge Charles R. Breyer, we are assigning this litigation to a jurist experienced in complex multidistrict litigation and sitting in a district with the capacity to handle this litigation.

IT IS THEREFORE ORDERED that, pursuant to 28 U.S.C. § 1407, the actions listed on the attached Schedule A and pending outside the Northern District of California are transferred to the

Northern District of California and, with the consent of that court, assigned to the Honorable Charles R. Breyer for coordinated or consolidated pretrial proceedings with the action pending there and listed on Schedule A.

IT IS FURTHER ORDERED that the actions in MDL-1691, MDL-1693 and MDL-1694 are merged into MDL-1699 *In re Bextra and Celebrex Marketing, Sales Practices and Products Liability Litigation.*

FOR THE PANEL:

Wm. Terrell Hodges
Chairman

SCHEDULE A

MDL-1699 -- In re Bextra and Celebrex Marketing, Sales Practices and Products Liability Litigation

Northern District of Alabama

Darryl Blue, etc. v. Pfizer, Inc., C.A. No. 2:05-464
Martha Ann Lemond, et al. v. Merck & Co., Inc., et al., C.A. No. 7:05-691

District of Arizona

Dorothy Greaves v. Pfizer, Inc., et al., C.A. No. 2:05-647

Central District of California

John Bolwell, et al. v. Pfizer, Inc., C.A. No. 2:05-1967

Northern District of California

June Swan, et al. v. Pfizer, Inc., et al., C.A. No. 3:05-834

District of Connecticut

Kenneth Kaye, et al. v. Pfizer, Inc., C.A. No. 3:05-385
Irene Bailey, et al. v. Pfizer, Inc., et al., C.A. No. 3:05-386

District of Delaware

Ronnie L. Hatcher v. Pfizer, Inc., et al., C.A. No. 1:05-208

Northern District of Florida

Marie McConnell v. Pfizer, Inc., C.A. No. 3:05-123

Southern District of Florida

Aurora Balloveras v. Pfizer, Inc., C.A. No. 1:05-20429

Eastern District of Louisiana

Gloria Ward v. Pfizer, Inc., C.A. No. 2:04-3469
Elmer E. Creel, Sr., et al. v. Pfizer, Inc., C.A. No. 2:04-3470
Carol J. Aiola v. Pfizer, Inc., C.A. No. 2:05-1207

Ronald J. Babin v. Pfizer, Inc., C.A. No. 2:05-1208
Deborah Ann Woodberry v. Pfizer, Inc., C.A. No. 2:05-1350
Terry Bridges v. Pfizer, Inc., C.A. No. 2:05-1353
George Hoffman v. Pfizer, Inc., C.A. No. 2:05-1354
Helen Anne Todini v. Pfizer, Inc., C.A. No. 2:05-1367
Betty A. Alexander, et al. v. Pfizer, Inc., C.A. No. 2:05-1720

Middle District of Louisiana

Ronald W. Abel, etc. v. Pfizer, Inc., C.A. No. 3:05-258

Western District of Louisiana

William Doss Turner v. Pfizer, Inc., C.A. No. 1:05-619
Yvonne Clark v. Pfizer, Inc., C.A. No. 1:05-620

District of Massachusetts

Health Care for All, et al. v. Pfizer, Inc., et al., C.A. No. 1:05-10707

Eastern District of Michigan

Linda A. Watters, et al. v. Pfizer, Inc., et al., C.A. No. 2:05-71434

District of Minnesota

Loretta M. Harris v. Pfizer, Inc., C.A. No. 0:05-728

Eastern District of New York

Melissa Kelly, et al. v. Pfizer, Inc., C.A. No. 1:05-949

Southern District of New York

ASEA/AFSCME Local 52 Health Benefits Trust v. Pfizer, Inc., et al., C.A. No. 1:05-3803
Steamfitters' Industry Welfare Fund, et al. v. Pfizer, Inc., et al., C.A. No. 1:05-3814
Sheet Metal Workers' International Assn. v. Pfizer, Inc., et al., C.A. No. 1:05-4125

Northern District of Ohio

Theresa Blatnik, et al. v. Pfizer, Inc., C.A. No. 1:05-900

- A3 -

Southern District of Texas

Ronald L. Baker, et al. v. Pfizer, Inc., C.A. No. 3:05-206

JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

JOANN BURKEEN and LUCINDA ISOM

DEFENDANTS

Pfizer, Inc., a Delaware Corporation; Pharmacia Corporation, a Delaware Corporation; and G.D. Searle LLC, a Delaware Corporation

(b) County of Residence of First Listed Plaintiff State of Tennessee
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant AGENT FOR SERVICE OF PROCESS IN MPLS., MN
(IN U.S. PLAINTIFF CASES ONLY)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Martha K. Wivell, Esq., #0128090
Suite 1025 Fifth Street, 100 South Fifth Street
Minneapolis, MN 55402
Telephone: (612) 767-7500

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal

PERSONAL INJURY
- ☐ 362 Personal Injury—Med. Malpractice
- ☒ 365 Personal Injury — Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/ Disabilities Employment
- ☐ 446 Amer. w/ Disabilities – Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt Relations
- ☐ 730 Labor/Mgmt Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc Security Act

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/etc
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statues

V. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

☒ 1 Original Proceeding | ☐ 2 Removed from State Court | ☐ 3 Remanded from Appellate Court | ☐ 4 Reinstated or Reopened | ☐ 5 Transferred from another district (specify) | ☐ 6 Multidistrict Litigation | ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. Section 1332
Brief description of cause: Products Liability

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $ In excess of $75,000

CHECK YES only if demanded in complaint.
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions). MDL 1699 Northern District of California

JUDGE DOCKET NUMBER MDL 1699

DATE 11/20/07

SIGNATURE OF ATTORNEY OF RECORD Martha K. Wivell

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

JOANN BURKEEN and LUCINDA ISOM,	**Case No.: 07-CV-4671-MJD/AJB**
Plaintiffs,	
v.	
PFIZER, INC., PHARMACIA CORPORATION, and G.D. SEARLE LLC,	**DEFENDANTS PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE LLC'S ANSWER TO PLAINTIFFS' COMPLAINT**
Defendants.	**Jury Trial Demanded**

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia") and G.D. Searle LLC ("Searle") and file this Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as follows:

I.
ORIGINAL ANSWER

Response to Introduction

1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny any wrongful conduct, deny that that Celebrex® is defective or

unreasonably dangerous, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

2. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that this case should be transferred to In re: Celebrex and Celebrex Marketing, Sales Prac. and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005. Defendants deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Parties

3. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York, and that Pfizer does business in the State of Minnesota. Defendants admit that, as the result of a merger in April 2003, Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

6. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000, and, that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

7. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000, and, that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

8. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Pharmacia acquired Searle in 2000, and,that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this paragraph of the Complaint.

9. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

10. Defendants deny the allegations in this paragraph of the Complaint.

Response to Allegations Regarding Jurisdiction and Venue

11. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim that the parties are diverse and the amount in controversy exceeds $75,000, exclusive of interests and costs.

12. Defendants admit that Pfizer is registered to do business in the State of Minnesota. Defendant admits that Pfizer maintains a registered agent in the State of Minnesota. Defendants deny the remaining allegations in this paragraph of the Complaint.

13. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

14. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny committing a tort in the State of Minnesota, and deny the remaining allegations in this paragraph of the Complaint.

16. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of Minnesota. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

Response to Factual Allegations

17. Defendants state that the allegations in this paragraph of the Complaint regarding aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as being non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendants deny the

remaining allegations in this paragraph of the Complaint.

18. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

19. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

20. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

21. Defendants state that the allegations in this paragraph of the Complaint regarding "other pharmaceutical companies" are not directed toward Defendants, and, therefore, no response is required. To the extent a response is deemed required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme." Plaintiffs fail to provide the proper context for the remaining allegations in this paragraph. Defendants therefore lack knowledge or information

sufficient to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in this paragraph of the Complaint.

22. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme." Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

23. Defendants admit that Searle submitted a New Drug Application ("NDA") for Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults. Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis ("FAP") as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny the remaining allegations in this paragraph of the Complaint.

24. Defendants admit that Celebrex® was launched in February 1999. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,

which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

25. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

26. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

27. Defendants state that the referenced FDA Update speaks for itself and respectfully refer the Court to the FDA Update for its actual language and text. Any attempt to characterize the FDA Update is denied. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

28. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

29. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

30. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to characterize it is denied. Defendants admit that a Medical Officer Review dated September 20, 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

31. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

32. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

33. Defendants state that the FDA Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

34. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee

hearings speak for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to characterize the transcripts is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

35. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

36. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

37. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

38. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

39. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

40. Plaintiffs fail to provide the proper context for the allegations concerning "Public Citizen" in this paragraph of the Complaint. Defendants therefore lack knowledge or

information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

41. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

42. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Plaintiffs fail to provide the proper context for the allegations concerning "Public Citizen" in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

43. Defendants admit that there was a clinical trial called APC. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

44. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Plaintiffs fail to provide the proper context for the allegations concerning "Data Safety Monitoring Board" in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

45. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

46. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language

and text. Any attempt to characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

47. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

48. Defendants admit that there was a clinical trial called PreSAP. Plaintiffs fail to provide the proper context for the allegations concerning "other Celebrex trials" contained in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. As for the allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

49. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

50. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that the referenced studies speak for themselves and respectfully refer the Court to the studies for their actual language and text. Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

51. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining

allegations in this paragraph of the Complaint.

52. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Vioxx® in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

53. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

54. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants state that the

referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

55. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this paragraph of the Complaint.

56. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

57. Defendants state that allegations in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

58. Defendants deny the allegations in this paragraph of the Complaint.

59. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations contained in this paragraph of the Complaint.

60. Defendants deny any wrongful conduct and deny the allegations contained in this paragraph of the Complaint.

61. Defendants deny any wrongful conduct and deny the allegations contained in this paragraph of the Complaint.

62. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations contained in this paragraph of the Complaint.

63. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

64. Defendants admit that the FDA Division of Drug Marketing, Advertising, and Communications ("DDMAC") sent letters to Searle dated October 6, 1999, April 6, 2000, and November 14, 2000. Defendants state that the referenced letters speak for themselves and respectfully refer the Court to the letters for their actual language and text. Any attempt to characterize the letters is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

65. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

66. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

67. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005.

Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

68. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

69. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for

relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

70. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the allegations in this paragraph of the Complaint.

71. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining

allegations in this paragraph of the Complaint.

72. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

73. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

74. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

75. Defendants deny the allegations in this paragraph of the Complaint.

76. Defendants state that Celebrex® was and is safe and effective when used in accordance

with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

77. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

78. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

79. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

80. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

the Complaint.

81. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

82. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

83. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

Response to Plaintiffs' Individual Statements of Facts

84. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

85. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

86. Defendants deny any wrongful conduct, that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

87. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

88. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition and whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

89. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants

state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

90. Defendants deny any wrongful conduct, that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to First Cause of Action: Strict Liability

91. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

92. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

93. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with

applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

94. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

95. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

96. Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

97. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Breach of Implied Warranty of Merchantability

98. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

99. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain

periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

100. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

101. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

102. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

103. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

104. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Third Cause of Action:
Breach of Implied Warranty of Fitness for a Particular Purpose

105. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

106. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

107. Defendants deny the allegations in this paragraph of the Complaint.

108. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

109. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

110. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

111. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

112. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

113. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fourth Cause of Action: Breach Express Warranty

114. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

115. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved

prescribing information regarding Celebrex®. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

116. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fifth Cause of Action: Negligence

117. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

118. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct , deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

119. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

120. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Demand For Judgment

Answering the unnumbered paragraph of the Complaint headed "Demand For Judgment Against Defendants Pfizer, Inc.; Pharmacia Corporation; and G.D. Searle LLC (FKA G.D. Searle

& Co.)," Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

II.
GENERAL DENIAL

Defendants deny the allegations and/or legal conclusions set forth in Plaintiffs' Complaint that have not been previously admitted, denied, or explained.

III.
AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiffs' action is barred by the statute of repose.

Seventh Defense

7. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiffs and Plaintiffs' damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiffs were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs' treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiffs was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the unforeseeable alteration, change, improper handling, abnormal use, or other unforeseeable misuse of Celebrex® by persons other than Defendants or persons acting on its behalf after the product left the control of Defendants.

Seventeenth Defense

17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

Nineteenth Defense

19. Plaintiffs knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 *et. seq.*

Twenty-first Defense

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

Twenty-third Defense

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution, Article I, § 17 of the Constitution of the States of Minnesota and Tennessee, and would

additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Minnesota and Tennessee law, including, but not limited to, Minn. Stat. § 549.191 (2006).

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiffs' punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiffs failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of Minnesota and Tennessee. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiffs.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiffs would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the

claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs.

Fifty-second Defense

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendants affirmatively aver that the product at issue complied with all government standards as referred to in T.C.A. § 29-28-104 and said product was not then at the time of manufacture and sale and is not now in an unreasonably dangerous condition in regard to matters covered by these standards and Defendants plead the Tennessee Products Liability Act of 1978, T.C.A. § 29-28-101, *et seq.,* in full bar of any liability on the part of Defendants.

Fifty-sixth Defense

56. Defendants affirmatively aver that Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, T.C.A. Section 28-3-104, and same is pled in full bar of any liability as to Defendants.

Fifty-seventh Defense

57. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

IV.
JURY DEMAND

Defendants hereby demand a trial by jury.

V.
PRAYER

WHEREFORE, Defendants pray that Plaintiffs take nothing by their suit; that Defendants be discharged with their costs expended in this matter, and for such other and further relief to which it may be justly entitled.

Dated: December 10, 2007.

FAEGRE & BENSON LLP

/s/ Joseph M. Price

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Erin M. Verneris # 0335174
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Attorneys for Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC

fb.us.2473354.02

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: BEXTRA AND CELEBREX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION

MDL No. 1699

(SEE ATTACHED SCHEDULE)

CONDITIONAL TRANSFER ORDER (CTO-91)

On September 6, 2005, the Panel transferred 30 civil actions to the United States District Court for the Northern District of California for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* 391 F.Supp.2d 1377 (J.P.M.L. 2005). Since that time, 1,164 additional actions have been transferred to the Northern District of California. With the consent of that court, all such actions have been assigned to the Honorable Charles R. Breyer.

It appears that the actions on this conditional transfer order involve questions of fact that are common to the actions previously transferred to the Northern District of California and assigned to Judge Breyer.

Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), these actions are transferred under 28 U.S.C. § 1407 to the Northern District of California for the reasons stated in the order of September 6, 2005, and, with the consent of that court, assigned to the Honorable Charles R. Breyer.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Northern District of California. The transmittal of this order to said Clerk shall be stayed 15 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 15-day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:

Jeffery N. Lüthi
Clerk of the Panel

I hereby certify that the annexed instrument is a true and correct copy of the original on file in my office.
ATTEST:
RICHARD W. WIEKING
Clerk, U.S. District Court
Northern District of California
By _____ Deputy Clerk
Date 1-7-08

IN RE: BEXTRA AND CELEBREX MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION MDL No. 1699

SCHEDULE CTO-91 - TAG-ALONG ACTIONS

DIST.	DIV.	C.A. #	CASE CAPTION
FLORIDA MIDDLE			
FLM	8	07-2011	Vincent Rosenquist, et al. v. Pfizer Inc.
MARYLAND			
MD	1	07-3130	Alex Bondarenko v. Pfizer Inc.
MD	1	07-3131	Melvin Brown v. Pfizer Inc.
MD	1	07-3133	Theodore Carter v. Pfizer Inc.
MD	1	07-3134	Hobert Church, Jr. v. Pfizer Inc.
MD	1	07-3135	Gary Cox v. Pfizer Inc.
MD	1	07-3136	Raymond Deigert v. Pfizer Inc.
MD	1	07-3137	Dana Johnson v. Pfizer Inc.
MD	1	07-3138	Ruth Logan v. Pfizer Inc.
MD	1	07-3139	Nora Manning v. Pfizer Inc.
MD	1	07-3140	Esther Nimarko v. Pfizer Inc.
MD	1	07-3141	Carolyn Owens v. Pfizer Inc.
MD	1	07-3142	George Sherain, II v. Pfizer Inc.
MD	1	07-3143	Inetta Wood v. Pfizer Inc.
MINNESOTA			
MN	0	07-4634	Vivian Cobb v. Pfizer Inc., et al.
MN	0	07-4661	Gene Summers v. Pfizer Inc., et al.
MN	0	07-4662	Ed Narke v. Pfizer Inc., et al.
MN	0	07-4670	Charlotte Allen, et al., Pfizer Inc., et al.
MN	0	07-4671	Joann Burkeen, et al. v. Pfizer Inc., et al.
MISSISSIPPI NORTHERN			
MSN	4	07-124	Claiborne Leon Collier, Sr., et al. v. Pfizer Inc., et al.

OFFICE OF THE CLERK
UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

Richard W. Wieking
Clerk

450 Golden Gate Avenue
San Francisco, CA 94102
415.522.2000

January 7th, 2008

Minnesota District Court
300 South Fourth Street
Minneapolis, MN 55415

Re: MDL 05-1699 In re Bextra and Celebrex Marketing, Sales Practices and Products Liability Litigation

Title of Case(s)	Your Case Number(s)
Joann Burkeen, et al. v. Pfizer Inc.	C.A. No. 07-4671

Dear Clerk:

Enclosed is a certified copy of the order from the Judicial panel on Multidistrict Litigation transferring the above entitled action to the Northern District of California, San Francisco Division. The case has been assigned to the Honorable Charles R. Breyer for coordinated or consolidated pretrial processing pursuant to 28 USC §1407.

Please forward the **original record** and **a certified copy of the docket entries** in the case listed above along with the enclosed copy of this transmittal letter to:

United States District Court
Northern District of California
450 Golden Gate Avenue, P.O. Box 36060
San Francisco, CA 94102
Attn: Simone Voltz

If the case is an electronic case filing please do one of the following: 1) e-mail the PDF documents, as separate PDF files, including a PDF copy of the docket sheet to **SFmdl_clerk@cand.uscourts.gov**, 2) provide us with a temporary log in and a password to directly access your database and to expedite the downloading of the PDF files we need and/or require, or, 3) if you prefer, on a disc. We appreciate your prompt attention to this matter.

Sincerely yours,
Richard W. Wieking, Clerk

Simone Voltz

By: Simone Voltz
Deputy Clerk

Encl.

CLOSED, CV

U.S. District Court
U.S.District Court Minnesota (DMN)
CIVIL DOCKET FOR CASE #: 0:07-cv-04671-DWF-SRN
Internal Use Only

Burkeen et al v. Pfizer Inc. et al
Assigned to: Judge Donovan W. Frank
Referred to: Magistrate Judge Susan R. Nelson
Demand: $75,000
Cause: 28:1332-pip-Diversity-Personal Injury, Product Liability

Date Filed: 11/20/2007
Jury Demand: Plaintiff
Nature of Suit: 365 Personal Inj. Prod. Liability
Jurisdiction: Diversity

Plaintiff

Joann Burkeen

represented by **Elizabeth-NA L. Dudley**
Not Admitted
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Mark-NA B. Hutton
Not Admitted
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ATTORNEY TO BE NOTICED

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Plaintiff

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Mark-NA B. Hutton
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Martha K Wivell
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ATTORNEY TO BE NOTICED

V.

Defendant

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ATTORNEY TO BE NOTICED

Defendant

Pharmacia Corporation

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LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Joseph M Price
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

G.D. Searle LLC
formerly known as
G.D. Searle & Co.

represented by **Erin M Verneris**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Joseph M Price
(See above for address)
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
11/20/2007	1	COMPLAINT against all defendants (Filing fee $ 350 receipt number 17807.) assigned to Judge Donovan W Frank per Master List referred to Magistrate Judge Arthur J Boylan., filed by Joann Burkeen, Lucinda

		Isom. (Attachments: # 1 Complaint part 2 # 2 Exhibit(s) A # 3 Civil Cover Sheet) (jdf) (Entered: 11/20/2007)
11/20/2007		Summons Issued as to Pfizer Inc., Pharmacia Corporation, G.D. Searle LLC. (dch) (Entered: 11/21/2007)
11/20/2007		(Court only) *** Copy of complaint sent to the MDL Panel (dch) (Entered: 11/21/2007)
11/21/2007	2	SUMMONS Returned Executed by Joann Burkeen. Pfizer Inc. served on 11/21/2007, answer due 12/11/2007. (Randall, Stephen) (Entered: 11/21/2007)
11/21/2007	3	ORDER OF RECUSAL. Magistrate Judge Arthur J. Boylan recused. Case reassigned to Magistrate Judge Susan R. Nelson for all further proceedings. The new case number is 07cv4671 DWF/SRN. Signed by Magistrate Judge Arthur J. Boylan on 11/21/07. (JME) (Entered: 11/21/2007)
12/10/2007	4	ANSWER to Complaint with Jury Demand by Pfizer Inc., Pharmacia Corporation, G.D. Searle LLC. (Price, Joseph) (Entered: 12/10/2007)
12/10/2007	5	RULE 7.1 DISCLOSURE STATEMENT by Pfizer Inc., Pharmacia Corporation, G.D. Searle LLC that there is no such parent or publicly held corporation to report. (Price, Joseph) (Entered: 12/10/2007)
12/10/2007	6	CERTIFICATE OF SERVICE by Pfizer Inc., Pharmacia Corporation, G.D. Searle LLC re 4 Answer to Complaint, 5 Rule 7.1 - Disclosure Statement (Price, Joseph) (Entered: 12/10/2007)
12/10/2007		(Court only) *** Attorney Erin M Verneris for Pfizer Inc. and Pharmacia Corporation added. (dch) (Entered: 12/10/2007)
12/31/2007	7	SUMMONS Returned Executed by Joann Burkeen, Lucinda Isom. Pharmacia Corporation served on 11/21/2007, answer due 12/11/2007. (Wivell, Martha) (Entered: 12/31/2007)
12/31/2007	8	SUMMONS Returned Executed by Joann Burkeen, Lucinda Isom. G.D. Searle LLC served on 11/21/2007, answer due 12/11/2007. (Wivell, Martha) (Entered: 12/31/2007)
01/10/2008	9	CERTIFIED COPY OF THE CONDITIONAL TRANSFER ORDER (CTO-91), transferring case to the Northern District of California for coordinated or consolidated proceedings. Case assigned to the Honorable Charles R Breyer. (jdf) (Entered: 01/11/2008)
01/11/2008	10	LETTER Case has been transferred via e-mail to the Northern District of California pursuant to CTO. (jdf) (Entered: 01/11/2008)

A true printed copy in 3 sheet(s)
of the electronic record filed on _____,
in the United States District Court
for the District of Minnesota.
CERTIFIED, January 11, 2008.
RICHARD D. SLETTEN
BY: Jennifer Buckman Fennerne
Deputy Clerk